

POLICY Document for Myobloc

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, and overall clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product

- Policy information specific to preferred medications

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA BOTULINUM TOXINS

I. PREFERRED PRODUCTS: BOTOX, DYSPORT

This policy informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

II. PLAN DESIGN SUMMARY

This program applies to the botulinum toxins products specified in this policy. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a non-preferred product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Botulinum Toxins

	Product(s)
Preferred	<ul style="list-style-type: none"> • Botox (onabotulinumtoxinA) • Dysport (abobotulinumtoxinA)
Non-preferred	<ul style="list-style-type: none"> • Myobloc (rimabotulinumtoxinB) • Xeomin (incobotulinumtoxinA)

III. EXCEPTION CRITERIA

Coverage for a non-preferred product is provided when ANY of the following criteria is met:

- A. Member is currently receiving treatment with the non-preferred product through health insurance, excluding when the non-preferred product is obtained as samples or via manufacturer's patient assistance programs.
- B. Member has had an inadequate response or an intolerable adverse event to both preferred products.
- C. Member is requesting Xeomin for the treatment of blepharospasm and has had an inadequate response or an intolerable adverse event to Botox.

Section 2: Clinical Criteria

MYOBLOC (rimabotulinumtoxinB)

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Cervical dystonia in adults to reduce the severity of abnormal head position and neck pain associated with cervical dystonia

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage will not be provided for cosmetic use.

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for treatment of cervical dystonia (e.g., torticollis).

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

REFERENCES:

SECTION 1

1. Botox [package insert]. Irvine, CA: Allergan, Inc.; April 2017.
2. Dysport [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; December 2016.
3. Myobloc [package insert]. City, ST: Solstice Neurosciences, Inc.; May 2010.
4. Xeomin [package insert]. Frankfurt, Germany: Merz Pharmaceuticals GmbH; December 2015.

SECTION 2

1. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; May 2010.
2. DRUGDEX® System [Internet database]. Ann Arbor, MI: Truven Health Analytics. Updated periodically. Accessed August 31, 2016.